

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	
_____	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	
	)	Subcategory No. 06-11337-PBS
<i>United States of America ex rel. Ven-a-Care of</i>	)	
<i>the Florida Keys, Inc. v. Dey, Inc., et al., Civil</i>	)	
Action No. 05-11084-PBS	)	Hon. Patti B. Saris
	)	

**LEAVE TO FILE GRANTED ON MAY 4, 2010**

**REPLY MEMORANDUM IN SUPPORT OF MOTION TO BIFURCATE**

Dey makes a three-pronged attack on plaintiffs’ motion to bifurcate the Medicare claims for a separate trial from the Medicaid claims. All three arguments fail. Bifurcation is warranted where, as here, it leads to significant economies, conserves the Court’s and parties’ resources, and preserves defendants’ right to a jury trial.

**I. Bifurcation Will Not Violate the Seventh Amendment**

Dey contends that bifurcation would violate its Seventh Amendment rights because it “will result in multiple juries considering the same factual issues.” Dey Mem., 2. The only factual issue Dey identifies as likely to be resolved by multiple juries is its scienter. Specifically, Dey argues that the United States’ claims recognize “no distinction for Dey’s scienter as it relates to Medicaid as opposed to Medicare.” *Id.*, 4. Even if evidence relating to Dey’s scienter is similar for both programs, however, bifurcation does not run afoul of the Seventh Amendment.

Under the False Claims Act, the only factual issue relevant to determining Dey’s scienter is whether Dey knew, recklessly ignored, or was deliberately indifferent to the fact its prices were false. If Dey knew its reported prices greatly exceeded its actual prices, then Dey acted

“knowingly” in reporting false prices for purposes of determining its liability under the statute. The proof of Dey’s scienter therefore will be substantially similar for the Medicare and Medicaid claims, and Dey will suffer no prejudice from having this issue resolved by the first jury. The Court can avoid a Seventh Amendment issue by instructing the jury in the Medicaid trial of any issues that have already been decided, and by means of a special verdict form ensure that a jury finding favorable to Dey on an issue in the first trial would be preclusive of the same issue in the Medicaid trial. *See Robinson v. Metro-North Commuter R.R. Co.*, 267 F.3d. 147, 169 n.13 (2d Cir. 2001) (quoting Steven S. Gensler, *Bifurcation Unbound*, 75 Wash. L. Rev. 705, 736-37 (2000)) (“Trying a bifurcated claim before separate juries does not run afoul of the Seventh Amendment” so long as the Court “carefully craft[s] the verdict form for the first jury so that the second jury knows what has been decided already”); *Cayuga Indian Nation of New York v. Pataki*, 188 F. Supp. 2d 223, 232 (N.D.N.Y. 2002) (by “carefully defining the roles of the successive juries” it is “possible for courts to avoid running afoul of the Seventh Amendment”).

Alternatively, if the Court agrees with Dey that the “knowledge” element includes consideration of whether Dey reasonably could have believed that “AWP” was an industry term of art that had no meaning, and that this issue includes consideration of particular government employees’ understandings of the term, then the “knowledge” element in the Medicare context will be different than in the Medicaid context, and there will be no commonality.<sup>1</sup> No Seventh

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<sup>1</sup> A recent Supreme Court case undercuts Dey’s view of scienter. *See Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich LPA, et al.* ---S. Ct.---, 2010 WL 1558977, \*5 (2010) (recognizing the “common notion, familiar to all minds, that ignorance of the law will not excuse any person, either civilly or criminally,” and holding that an act may be “intentional” within meaning of Fair Debt Collection Practices Act (FDCPA) “even if the actor lacked knowledge that her conduct violated the law.”) The *Jerman* holding was premised on the fact that the FDCPA had no mistake-of-law defense to civil liability, suggesting that “Congress chose” to permit consumers to recover damages for “intentional” conduct, including “violations resulting from mistaken interpretations of

Amendment risk is implicated under those circumstances even if some of the evidence pertaining to scienter would be the same in both trials. *See, e.g., Houseman v. United States Aviation Underwriters*, 171 F.3d 1117, 1128 (7th Cir. 1999) (noting that “[t]he Seventh Amendment is concerned about factual conclusions not evidence”); *PaineWebber, Jackson & Curtis v. Merrill Lynch Pierce, Fenner & Smith*, 587 F. Supp. 1112, 1117 (D. Del. 1984) (holding that the Seventh Amendment’s prohibition “is not against having two juries review the same evidence, but rather against having two juries decide the same essential issues”).

Dey relies heavily on *Ingles v. City of New York*, No. 01 Civ. 08279 (DC), 2005 WL 1354028, \*1 (S.D.N.Y. June 7, 2005). Dey Mem., 3-4. The decision not to bifurcate in that case was based on considerations strikingly different from those present here. In particular, the *Ingles* case involved a certified class action alleging a pattern and practice of excessive force in New York City prisons against the City and nearly two dozen individual defendants, and included requests for “significant injunctive relief, including institutional and systemic reform.” *Id.* The Court’s refusal to grant the City’s request to bifurcate the action was based on concerns not present here, including that plaintiffs and ten of the defendants opposed bifurcation and that granting the request would have resulted in *twenty-two* separate trials.

## **II. Bifurcation Is Entirely Appropriate Under Rule 42(b)**

Dey argues that this is not an appropriate case for bifurcation because there will be a duplication of evidence and a needless “tie up” of judicial resources. Dey Mem., 5-9. Dey then attempts to demonstrate that virtually all categories of evidence would be “equally relevant” in both trials. The attempt falls short. First, Dey is incorrect in suggesting that the majority of

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the FDCPA.” *Id.* Like the FDCPA, the False Claims Act contains no mistake-of-law defense.

evidence concerning nearly 50 state Medicaid programs will be relevant and introduced in a Medicare-only trial. The views of a state employee in Arkansas about the workings of that state's Medicaid program have no relevance to the issues properly raised in a Medicare-only trial. The Medicare claims implicate a single reimbursement scheme, one based on AWP as a matter of law.<sup>2</sup> Both this Court and the First Circuit have spoken to the construction of AWP that will guide the jury's evaluation of the evidence. Much as Dey might like the jury in a Medicare case to hear testimony of some state Medicaid employees about their interpretations of AWP, such evidence would plainly be inappropriate in light of these earlier decisions.

Dey's argument that if the United States introduces any evidence that Dey "marketed the spread," there will be "no efficiencies" from bifurcation is myopic. Although Dey argues that such evidence "is of marginal use" in the Medicare context, most of the marketing evidence plaintiffs will offer pertains to the two drugs reimbursed by both programs, and many of Dey's marketing documents are directed to both Medicare and Medicaid. The admissibility of such evidence as to the Medicare claims, including any proffered 404(b) evidence, likely will be briefed and argued later.<sup>3</sup> In any event, the real savings to be gained from bifurcation derives from tabling the presentation of evidence as to scores of state Medicaid programs.

The proof is in the pudding. Dey's own Proposed Trial Plan (Master Dkt #7077, Sub.

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<sup>2</sup> Furthermore, in contrast to the central role that headquarters has always played in Medicare program operations, from approximately June 1990 until June 2002, HCFA/CMS Regional Offices had direct approval power for Medicaid state plan amendments.

<sup>3</sup> Dey's argument that the "spread" could not be used as marketing tool in the Medicare context is misleading, since pharmacies typically stock only one generic form of a particular drug, and do not distinguish between Medicare and Medicaid in buying decisions. Dey's marketing plans repeatedly described the company's strategy to "provide an incentive to retail and chain pharmacies to purchase Dey's [product] by increasing the spread on Medicare/Medicaid reimbursements."

#761), states Dey's view that a combined trial would take between three and four *months*, involve almost 2,000 more exhibits, including about twenty to "a few hundred" exhibits for each state. Together, the parties identify twice as many witnesses and nearly twice as many exhibits for a combined trial as for a Medicare-only trial. "The degree to which the issues overlap can often best be assessed by examining the amount of evidence and the number of witnesses that would be presented at both trials." *Willemijn Houdstermaastchaap BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1434 (D. Del. 1989). Here, although the United States and Dey disagree on the extent to which evidence of variations in individual state reimbursement mechanisms is needed, given underlying similarities and summary evidence of state methodologies and claims, it remains true that trial of the Medicaid claims will increase the amount and complexity of the evidence. In light of the increased volume of evidence, complexity of issues, risk of juror confusion, and consumption of judicial resources in a combined trial, it is well within this Court's broad discretion under Rule 42(b) to bifurcate the claims.

Dey also argues plaintiffs have not identified "any real efficiency" because subsequent settlement of the Medicaid claims is not certain. The case Dey cites from the Northern District of Indiana, Dey Mem. at 9-10, is inapposite. There, the court indicated bifurcation was inappropriate where the benefits of bifurcation would be realized only under one possible outcome of the first trial. *Fall v. Indiana Univ. Bd. of Trustees*, 33 F. Supp. 2d 729, 738 (N.D. Ind. 1998). Here, given that the Medicare claims encompass the majority of claimed damages, a jury verdict on those would provide tremendous incentive for both the prevailing and non-prevailing parties to resolve the Medicaid claims short of a second trial. Whether determination of an issue "might enhance the likelihood of settlement" is an appropriate consideration under

Rule 42(b). *See In re: Beverly Hills Fire Litig.*, 695 F.2d 207, 216-217 (6th Cir. 1982); *Industrias Metálicas Marva, Inc., v. Lausell*, 172 F.R.D. 1, 2 (D. P.R. 1997).

### **III. Dey Will Not Suffer Unfair Prejudice From Bifurcation**

Dey's third argument, Dey Mem., 10-12, need not detain the Court. The Medicare claims involve a single agency, fewer drugs, and the majority of damages. It is rational and practical to try those claims separately from those that implicate 47 separate agencies, a different statutory scheme, a different (and longer) damages period, more drugs, significantly more disputed expert and factual evidence, and 76 additional witnesses according to Dey's own list, yet less than a third of the damages. At bottom, Dey's real opposition appears to be that it will not be able to bolster its defense of the Medicare claims through presentation of disparate "government knowledge" testimony from some state Medicaid employees that it hopes the jury will impute to the federal government.

Respectfully submitted,

TONY WEST  
ASSISTANT ATTORNEY GENERAL

CARMEN M. ORTIZ  
UNITED STATES ATTORNEY

Joyce R. Branda  
Daniel R. Anderson  
Laurie A. Oberembt  
Civil Division  
Commercial Litigation Branch  
P. O. Box 261  
Ben Franklin Station  
Washington, D.C. 20044  
(202) 514-3345

By: /s/ Barbara Healy Smith  
George B. Henderson, II  
Barbara Healy Smith  
James J. Fauci  
Assistant U.S. Attorneys  
United States Courthouse  
1 Courthouse Way, Suite 9200  
Boston, MA 02210  
(617) 748-3272

FOR THE RELATOR,

James J. Breen  
The Breen Law Firm, P.A.  
5755 Northpoint Parkway, Suite 260  
Alpharetta, GA 30022  
Tel. (770) 740-000  
fax: (954) 499-1173

Gary Azorsky  
Susan Schneider Thomas  
Roslyn G. Pollack  
Berger & Montague, P.C.  
1622 Locust St.  
Philadelphia, PA 19103  
(215) 875-3090

#### CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: May 5, 2010

/s/ George B. Henderson, II  
George B. Henderson, II  
Assistant U.S. Attorney